

BK

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
6 December 2001 (06.12.2001)

PCT

(10) International Publication Number
WO 01/91631 A1

(51) International Patent Classification⁷: **A61B 5/00**

(21) International Application Number: PCT/AU01/00634

(22) International Filing Date: 29 May 2001 (29.05.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PQ 7824 29 May 2000 (29.05.2000) AU

(71) Applicant and

(72) Inventor: LEWIS, Richard, Hamilton [AU/AU]; 21
Lyllal Street, Shenton Park, Western Australia 6008 (AU).

(74) Agent: WRAY & ASSOCIATES; 239 Adelaide Terrace,
Perth, W.A. 6000 (AU).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK,
SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA,
ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 01/91631 A1

(54) Title: A SLEEP STUDY APPARATUS

(57) Abstract: An apparatus for detecting, processing and storing physiological signals obtained from a patient during sleep or wakefulness comprising at least one sensor housing. Each sensor housing includes at least one electrode and/or sensor (20a, 20b, 20c), a microprocessor (14) and associated memory (16). The microprocessor (14) responds to signals from said sensors (20a, 20b, 20c) to store data therefrom in the memory (16). Each sensor housing includes a means for communicating data in the memory (16) to an external device after signal collection has finished. The sensor housing includes adhesive or other suitable retention mechanism to hold the sensor housings to the patient's skin.

"A Sleep Study Apparatus"

Field of the Invention

This invention relates to monitoring physiological signals from patients in the setting of a sleep study.

5 Background Art

In the last 20 to 30 years the medical profession has become increasingly aware of sleep-related disorders, especially Obstructive Sleep Apnoea (OSA). OSA is thought to affect 2% of women and 4% of men above the age of thirty in the USA. It is correlated with an increased incidence of coronary artery disease,
10 hypertension, stroke, cardiac arrhythmias and a number of other serious conditions. Patients may also suffer from excessive daytime somnolence, poor concentration, depression, memory loss and sexual dysfunction.

A method to diagnose OSA using the sleep study or polysomnogram (PSG) was described in 1974 by Holland, Dement and Raynall. There are four levels of PSG.
15 The level 1 PSG, which is the most complete study, is performed in a sleep laboratory. It measures the following parameters:

- Electroencephalogram (EEG)
- Left and right electro-oculogram (EOG)
- Submental electromyogram (EMG)
- 20 • Nasal or oral airflow
- Respiratory movement or airflow
- Oximetry
- Electrocardiogram (ECG)
- Leg EMG
- 25 • Sleeping position.

- 2 -

In the sleep laboratory, the patient has multiple electrodes /sensors applied to the body, which are connected by wires to either separate monitors or to a central unit worn on the chest and fastened by straps around the torso. The central unit receives all the electrode /sensor leads and is in turn connected to a receiving
5 computer by a cable. The information is processed and a detailed sleep study report is produced. These are commonly computer generated and checked by a physician.

The level 1 PSG is the accepted standard for the diagnosis and determination of the severity and treatment of OSA. It is however expensive, labour intensive and
10 time consuming, as well as being inconvenient to patients who often suffer from "first night effects" due to sleeping in a foreign environment.

The level 2 PSG measures similar parameters to the level 1 study. Level 2 home sleep studies are currently performed in many countries. They require the patient to attend an office or clinic to have the electrodes / sensors placed on them by a
15 skilled technician before returning home. Some of the home study kits have a recording unit, which is strapped to the chest or abdomen and receives all the electrode / sensor wires. Others use a recording unit on the bedside table into which the leads from the electrodes /sensors are plugged. In both formats, the leads are exposed and prone to being pulled off inadvertently by the patient
20 during the night, and therefore devaluing the remaining data collected. The entire apparatus is returned to the sleep laboratory for data extraction and analysis.

Level 3 studies are partial home studies and level 4 studies are very limited home studies or screening studies measuring only 2 or 3 parameters. They have fairly low sensitivity as a screening tool.

25 In US patent 5 813 993, Kaplan et al teach a system of analysing the EEG to detect drowsiness, in particular analysing frequencies above 30Hz. The frequencies that are important in determining stages of sleep, however, are those frequencies from 0 to 14Hz. Furthermore the invention concerns drowsiness detection, not the recording of the physiological parameters of sleep.

- 3 -

US patent 5 133 346 describes an apnoea monitoring system which can be used for home sleep studies. The system only detects the ECG and chest and abdominal wall expansion and so represents a level 4 PSG. The patient is connected by wires to a receiving unit with all of the inherent problems associated with wiring in sleep studies. The data is stored on a cartridge, which may be mailed in for later analysis.

In US patent 5 928 133, Halyak describes a sleep monitoring and awakening device that does not store information to perform a sleep study, but rather provides a means for waking a patient up during a light plane of sleep. The patient is connected to the device by a cable, although Halyak mentions that it is possible to transmit the data by electromagnetic signal to a receiving station.

In US patent 5 275 159, Griebel describes a method and apparatus for diagnosing sleep disorders comprising three ECG electrodes, a laryngeal microphone, a finger oximeter, and a position pickup. The electrodes on the patient are connected to a receiving unit by wires, although mention is made that the signals could be transmitted to the unit by electromagnetic waves. No data are collected on EEG, EOG, airflow or respiratory effort which are required to accurately diagnose sleep disorders.

WO99 34864 by Hadas teaches a sleep apnoea screening system. This comprises a thermistor mounted on a plastic housing which sticks to the upper lip, and contains a battery and circuitry to detect apnoeas, and expresses the number of these via a non-volatile coloured marker on the plastic housing. It is unable to determine whether or not an apnoea is central or obstructive, and does not store in a digital form detailed information about the apnoeic events. Furthermore it does not collect all the abovementioned data required to diagnose sleep disorders.

US patent 4 802 485 to Bowers et al describes a monitoring system that samples data at the rate of each pulse beat of the patient, and the data is transferred to a recording unit near to the patient by wires. However, the system described by Bowers et al does not record EEG, EOG, ECG, body position or limb EMG.

US patent 5 902 250 by Verrier et al monitors eyelid movements as a guide to REM sleep, the ECG rate variability and morphology, and head movements of a patient to assess cardiorespiratory risk. It does not record the EEG, O₂ saturation, airflow, abdominal or chest wall movement, or limb movements. Furthermore
5 wires carry the signals to a receiving and processing unit carried on the patient or near to the patient.

Takashi in JP92 34189 describes an abdominal sensor which senses movements of the chest or abdominal wall, and records the frequency of these and stores the information within the sensor apparatus. It is unable to detect or store any of the
10 many parameters described previously, which are required for diagnosis of sleep disorders.

US patent 5 187 657 to Forbes teaches a system comprising EOG electrodes, two sets of ECG electrodes and a blood pressure monitor, with recording only occurring during REM sleep. The data are carried by wires to an external
15 receiving unit. This is a cardiac analyser and is not applicable to sleep studies.

US patent 3 774 593 by Hakata et al describes the collection of an EEG, EOG and EMG, and the transfer of said signals via wires to a receiving unit where the data are recorded on a magnetic tape. There is no recording of ECG, airflow, respiratory effort, body position or limb movements.

20 Bowman in US patent 4 999 772 describes a sleep screening system for recording on tape an ECG, air flow, impedance and pulse oximetry signal, and housing the tape in a portable recorder. There is no recording of EEG, body position or limb EMG, and the sensors are connected to the recorder by wires.

Hobson et al, in US patent 4 836 219 describes a sleep monitor headgear
25 detecting eyelid movements via a piezo-electric sensor, and head movements. The sensors are carried on headbands, and data carried via wires to an extraneous recording device or, in another possible embodiment, recorded in a data storage device carried on the headband. No recording of the other parameters required for a sleep study is made, and the headgear described does

not adhere to the forehead or measure the combination of parameters required for a sleep study.

As described above, the prior art in this field do not record many of the signals required for an accurate sleep study. Further, most use wires to connect the patient to a recording device, which may interfere with the patient's normal sleeping pattern and thus not give data representative of the patient condition. Further, the use of wire carries with it the risk of wires being disconnected resulting in a loss of data.

Disclosure of the Invention

10 Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

15 The purpose of this invention is to provide a robust, simple to apply, set of sensor housings that can be applied by the patient at home in order to conduct a comprehensive sleep test. The sensor housings are fashioned in such a way as to have minimal effect on the patient's sleep. They contain all the wiring, circuitry, data storage and power source within them so that there are no exposed wires.

20 After the sleep test the housings are returned to a nominated collection and interpretation centre where the stored data is downloaded and a sleep study report issued. Alternatively, the data can be extracted from the housings for storage and subsequent analysis.

25 The benefits for the patient are greater convenience and reduced waiting times for access to sleep laboratories. For the physician, the system will mean better quality home sleep study data, increased speed of diagnosis and quicker initiation of treatment.

In accordance with a first aspect of this invention, there is provided an apparatus for detecting, processing and storing physiological signals obtained from a patient during sleep or wakefulness comprising:

- 6 -

at least one sensor housing, each sensor housing comprising at least one sensor, processing means and associated storage means;

retention means arranged to hold each sensor housing to the patient's skin;

5 said processing means being responsive to signals from each said sensor to store data therefrom in said storage means; and

wireless means for communicating data in the storage means to an external device.

10 Preferably, the sensors are provided integrally with their respective sensor housings.

Preferably, each sensor housing includes a power source provided integrally therewith.

Preferably, the power source is detachable from the sensor housing.

15 Preferably, said processing means includes timer means, whereby signals stored by the processor means are time referenced.

In one arrangement, said processing means is arranged to commence storing data from the sensors upon receipt of signals therefrom corresponding to the sensor housing being placed on skin, and to stop storing data if said signals stop.

20 In an alternative arrangement, said timer means is arranged to signal the processing means for storage to commence storing data a predefined time after receipt of signals from the sensors corresponding to the sensor housing being placed on skin.

Preferably, the apparatus further comprises a plurality of sensor housings, each sensor housing having at least one sensor.

25 Preferably, the plurality of sensor housings comprise:

- 7 -

5 A first sensor housing arranged to be applied to the patient's head, the sensors of said first housing comprising at least one selected from the list of: an EEG sensor, an EOG sensor, a nasal and/or oral thermistor, a piezo-electric breath sensing device or quantitative air flow or air pressure meter, a pulse oximeter, an EMG sensor, a reference sensor; and

10 A second sensor housing arranged to be applied to the chest and abdomen, the sensors of the second housing comprising: at least two ECG electrodes, a patient position sensing device, a chest strain gauge or an impedance or inductance device to measure chest expansion, an abdominal strain gauge or an impedance or inductance measuring device to measure abdominal expansion, and a microphone for recording snoring and/or breathing sounds.

15 Preferably, the sensors of said first sensor housing comprise: an EEG sensor, an EOG sensor, a nasal and/or oral thermistor, a piezo-electric breath sensing device or quantitative air flow or air pressure meter, a pulse oximeter, an EMG sensor, a reference sensor.

20 Preferably, the sensors of said second sensor housing comprise: at least two ECG electrodes, a patient position sensing device, a chest strain gauge or an impedance or inductance device to measure chest expansion, an abdominal strain gauge or an impedance or inductance measuring device to measure abdominal expansion, and a microphone for recording snoring and/or breathing sounds.

25 In one arrangement, the sensor housings further comprise a third sensor housing having an EMG electrode.

In an alternative arrangement, the sensor housings further comprise a third sensor housing having an accelerometer arranged to be applied to a limb.

Preferably, the pulse oximeter is of the reflectance or transilluminance type.

Preferably, each sensor housing is made of plastics material.

- 8 -

Preferably, the storage means is detachable from the sensor housing.

Preferably, said processing means encrypts data stored in the storage means.

Brief Description of the Drawings

Figure 1 is a block diagram of a data module in accordance with the preferred
5 embodiment of the invention.

Best Mode(s) for Carrying Out the Invention

The embodiment is directed towards an apparatus that allows a PSG test to be performed in a patient's home, in a more patient-friendly and reliable manner than existing devices. Hopefully, this will obviate the need in the vast majority of cases
10 for referral to sleep laboratory for further sleep studies.

The preferred embodiment of the apparatus comprises three sensor housings, namely a head sensor housing, a chest sensor housing and a leg or other limb sensor housing.

Each sensor housing is arranged to automatically activate when fitted to a patient,
15 such as by detecting signals from the sensors. The sensor housings then enter a stand-by mode for one hour, and commence recording data at the end of the one hour stand-by. The sensor housings are also arranged to automatically switch off when removed from the patient.

The head sensor housing includes forehead, facial, ocular, nasal and oral
20 sections. The head sensor housing holds the following sensors:

- A pulse oximeter that, in the preferred embodiment, is of the reflectance type, and measures SaO₂ (oxygen saturation) by reflectance off the skull. The oximeter is contained within the forehead section of the head sensor housing. In an alternative embodiment the pulse oximeter can be of the conventional
25 trans-illuminating type, and applied to the ear lobe.
- An EEG sensor having two EEG electrodes that are built into the head sensor housing. When the housing is applied to the forehead, the EEG electrodes lie

over the frontal lobes, close to the frontal electrode positions of the standard international (10-20) electrode placement. The EEG electrodes are referenced to a reference electrode provided in the head sensor housing that, when the head sensor housing is applied to the head, rests on the mastoid, earlobe or similar position. The reference electrode sticks to the skin over the mastoid in the preferred embodiment. In an alternative embodiment it could be applied to the ear lobe.

• A facial muscle EMG electrode that is provided in the head sensor housing so as to measure any of the facial muscles. By convention in sleep studies, a chin EMG is used. In the preferred embodiment, the EMG part of the sensor housing is placed over the zygomaticus major muscle on the upper cheek. Alternatively, the EMG sensor could measure activity in the frontalis, procerus, corrugators or any other facial muscle. In still another embodiment a separate sensor housing with an EMG electrode in-built could be placed over the chin muscles.

• Two nasal and an oral thermistor. The use of thermistors is well known in the art for detecting airflow via temperature change. The thermistors are contained within an extension of the head sensor housing that passes down over the bridge of the nose, the columella and the philtrum of the upper lip. One thermistor protrudes into the nostril on each side, and the oral thermistor rests just above the upper lip. The applicant has also envisaged that in alternative embodiments, a piezo-electric sensor may be used to detect nasal and /or oral airflow instead of a thermistor. In yet another embodiment, airflow could be measured quantitatively by an air flowmeter.

• An EOG sensor having two EOG electrodes that are built into the head sensor housing. An EOG electrode is situated near the lateral canthus of each eye. In conformity with the PSG standard manual (Rechtschaffen and Kales, 1968) the EOG electrodes are offset from the horizontal, with one slightly (1cm) above and the other slightly below horizontal. Both electrodes are referenced to the reference electrode located over the mastoid, ear lobe or like position. Eye movements in REM sleep and wakefulness are binocularly synchronous. Eye movements are therefore recorded as out-of-phase deflections on the two

- 10 -

channels. Artefacts will be recorded as in-phase or in one channel only, and are therefore easily recognized. Piezo-electric sensors are used for the EOG electrodes in the embodiment.

The sensors are an integral part of the head sensor housing. That head sensor housing can be made of any flexible material, but preferably a soft foam polymer such as polyethylene. The above sensors in the head sensor housing are connected by wires or other suitable means to a data module in the head sensor housing that will be described below in detail. The wires are sandwiched within the substance of the head sensor housing, so that they are insulated from the skin, and they cannot be seen by the naked eye. The wires carry the signals to the data module.

The chest sensor housing includes chest and abdominal sections and contains the following sensors:

- At least two ECG electrodes. The ECG can be recorded from either 2 or 3 electrodes. In the preferred embodiment, 3 electrodes are used. The electrodes can be any commonly used for detecting an ECG. The ECG electrodes are built into the substance of the chest sensor housing. In the described embodiment, the electrodes lie at approximately the second right intercostal space, the midpoint of the left clavicle and a modified V5 position. The applicant is aware that many alternative electrode positions and numbers are valid, and these alternatives may be adopted without departing from the spirit and scope of the present invention. The described positions were chosen to provide reasonable ECG waveform morphology whilst minimizing the interference with chest hair in males.
- A means for detecting chest and abdominal respiratory effort to determine whether or not an apnoea is obstructive or central. In the described embodiment, the chest and abdominal respiratory efforts are measured by impedance. This is accomplished by placing 2 electrodes on the chest and 2 electrodes on the upper abdomen. The electrodes all use standard surface electrode technology well known in the art, and are built into the substance of the chest sensor housing. For best results, the patient is advised to shave the

- 11 -

area where the electrodes contact the skin, before applying that part of the chest sensor housing. In alternative embodiments, the chest and abdominal respiratory efforts can be detected using strain gauges or using inductance belts.

- 5 • A body position sensing device. The body position sensor is used to determine whether obstruction only occurs in certain sleeping positions. In the described embodiment, two mercury switches are mounted within the chest sensor housing, and are oriented to each other so that the position of the subject's torso is known at any time. In another embodiment, an electrically
- 10 conductive ball within a tetrahedron at whose corners are electrical contacts is used to provide body position information. These two techniques for position sensing are well known in the art, and these and any other position sensing devices may be used within the described chest sensor housing, and are thereby contained within the spirit and scope of the present invention.
- 15 • A microphone positioned near the sternal notch adjacent to the subject's trachea for recording snoring and / or breathing sounds. Any suitable type of acoustic pickup device may be used.

The wires leading from the sensors within the chest sensor housing are embedded within the substance of the housing in an identical fashion to the head

20 sensor housing. The wires terminate at the interface with the data module provided in the chest sensor housing.

By containing one of each of the chest and abdominal inductance sensors within a long, thin protrusion from the main substance of the chest sensor housing, the said two sensors are able to be stuck to the skin on the right side of the torso, and

25 thereby accommodate differing torso circumferences. These protrusions will not carry adhesive on their posterior surface except at their ends where the sensor is contained. This is to reduce the amount of hair that is contacted by adhesive, thereby reducing the patient's discomfort during removal of the housing.

In the level 1 PSG an EMG is recorded from each leg to detect leg movements

30 seen in conditions such as restless leg syndrome or nocturnal myoclonus, both of

- 12 -

which may be associated with daytime somnolence. In the embodiment a limb sensor housing containing an EMG electrode is applied to each leg over the tibialis anterior muscle.

5 Signals from the EMG electrode are carried by short wires contained within the limb sensor housing to an interface with the data module contained within the limb sensor housing.

The limb sensor housings may be produced in differing sizes according to where on the body they are to be placed. They can be used in any number or combination, but most commonly would be applied singly to each leg.

10 In other embodiments of the invention, EMG sensor housings containing several electrodes for application to the chin can be used to record the chin EMG as is described in the conventional PSG.

Each of the head sensor housing, the chest sensor housing and the limb or peripheral EMG sensor housings contain a data module and a power source.

15 Figure 1 is a block diagram of a data module 10 that comprises a signal conditioning circuit 12 a micro-processor 14, a storage device 16 and a timing circuit 18.

The data module 10 shown in figure 1 will be described with reference to a sensor housing containing three sensors 20a – 20c.

20 The signal conditioning circuit 12 comprises three amplifiers 22a – 22c each of which are responsive to one of the sensors 20a – 20c, respectively. The output of each amplifier 22a – 22c is input to a filter 24a – 24c to remove noise and unwanted frequency components in the amplified signal. The signal conditioning circuit 12 further comprises three analogue to digital converters 26a – 26c which
25 are responsive to the filtered signal from the filters 24a – 24c, respectively. The digitized signal from the analogue to digital converters 26a – 26c are input to a corresponding buffer, sample and hold circuit 28a – 28c. The output from each of the buffer, sample and hold circuits 28a – 28c are input to the microprocessor 14.

- 13 -

The microprocessor 14 receives signals from the buffer, sample and hold circuit 28a – 28c and processes the signals. Any suitable form of processing can be performed, including compression, encryption as well a signal analysis. Processed signals are stored in the data storage device 16 by the microprocessor

- 5 14. One suitable microprocessor is the 80L186ECR manufactured by Intel Corporation, although other microprocessors may be used.

The data storage device 16 can take any suitable form, such as non-volatile RAM.

- 10 The timing circuit 18 provides signals to the buffer, sample and hold circuits 28a – 28c and to the microprocessor 14 to synchronize operation thereof. Further, the timing circuit 18 provides a time signal to the microprocessor 14 so that data stored in the data storage device can be referenced relative to a time stamp. The time stamp is useful to allow data from multiple data modules to be time-correlated.

- 15 In the preferred embodiment of the invention, the data module is manufactured in a permanent fashion within the sensor housings, so that it is covered by a layer of the foam polymer material from which the housing is constructed, and so that it cannot be dislodged or tampered with. A suitable electrical interface allows the communication of the information stored within the storage device to an external system.

- 20 In an alternative embodiment, the data module will be inserted into a terminal within the sensor housings, ensuring a sturdy electrical contact, and fastened securely into place prior to shipping of the apparatus to the patient. Following completion of the test, the data module can be removed in the collection and interpretation centre for subsequent retrieval of the data and analysis thereof.

- 25 Table 1 below lists the sampling and storage of each of the sensor housing in the embodiment. It should be appreciated that the sampling and storage of each sensor in the sensor housings may be modified in other embodiments.

Table 1

Head Sensor Housing		No of Separate Sensors	Sample Rate Hz	Parameter	Quantisation Bits	No of Channels	Total bps	Mbytes Recorded
EEG sensor		3	512	Amplitude	9	3	13824	62.208
EOG Sensor		2	2	Amplitude	9	2	36	0.162
EMG Sensor		1	1	Amplitude	9	1	9	0.0405
Oxlemetry Module		1	2	Amplitude	9	1	18	0.081
Respiration Module		3	2	Amplitude	9	3	54	0.243
								62.7345
Chest Sensor Housing		No of Separate Sensors	Sample Rate Hz	Parameter	Quantisation Bits	No of Channels	Total bps	Mbytes Recorded
ECG		3	125	Amplitude	16	3	6000	27
Body Position Sensor		3	1	Amplitude	2	3	6	0.027
Chest and Abdominal Expansion Sensor		2	4	Amplitude	8	2	64	0.288
Tracheal Sound Sensor		1	10	Amplitude	8	1	80	0.36
								27.675
Leg Sensor Housing		No of Separate Sensors	Sample Rate Hz	Parameter	Quantisation Bits	No of Channels	Total bps	Mbytes Recorded
EMG Sensor		1	10	Amplitude	9	1	90	0.405

The Claims Defining The Invention Are As Follows:

1. An apparatus for detecting, processing and storing physiological signals obtained from a patient during sleep or wakefulness comprising:

5 at least one sensor housing, each sensor housing comprising at least one sensor, processing means and associated storage means;

 retention means arranged to hold each sensor housing to the patient's skin;

 said processing means being responsive to signals from each said sensor to store data therefrom in said storage means; and

10 wireless means for communicating data in the storage means to an external device.
2. The apparatus of claim 1, wherein the sensors are provided integrally with their respective sensor housings.
3. The apparatus of claim 1 or 2, wherein each sensor housing includes a power source provided integrally therewith.
- 15 4. The apparatus of claim 3, wherein the power source is detachable from the sensor housing.
5. The apparatus of any one of claims 1 to 4, wherein said processing means includes timer means, whereby signals stored by the processor means are time referenced.
- 20 6. The apparatus of any one of claims 1 to 5, wherein said processing means is arranged to commence storing data from the sensors upon receipt of signals therefrom corresponding to the sensor housing being placed on skin, and to stop storing data if said signals stop.
- 25 7. The apparatus of any one of claims 1 to 5, wherein said timer means is arranged to signal the processing means for storage to commence storing data a predefined time after receipt of signals from the sensors corresponding to the sensor housing being placed on skin.

8. The apparatus of any one of the preceding claims, further comprising a plurality of sensor housings, each sensor housing having at least one sensor.

9. The apparatus of claim 8, wherein the plurality of sensor housings comprise:

5 A first sensor housing arranged to be applied to the patient's head, the sensors of said first housing comprising at least one selected from the list of: an EEG sensor, an EOG sensor, a nasal and/or oral thermistor, a piezo-electric breath sensing device or quantitative air flow or air pressure meter, a pulse oximeter, an EMG sensor, a reference sensor; and

10 A second sensor housing arranged to be applied to the chest and abdomen, the sensors of the second housing comprising: at least two ECG electrodes, a patient position sensing device, a chest strain gauge or an impedance or inductance device to measure chest expansion, an abdominal strain gauge or an impedance or inductance measuring device to measure abdominal expansion, and a microphone for recording snoring
15 and/or breathing sounds.

10. The apparatus of claim 9, wherein the sensors of said first sensor housing comprise: an EEG sensor, an EOG sensor, a nasal and/or oral thermistor, a piezo-electric breath sensing device or quantitative air flow or air pressure meter, a pulse oximeter, an EMG sensor, a reference sensor.

20 11. The apparatus of claim 9 or 10, wherein the sensors of said second sensor housing comprise: at least two ECG electrodes, a patient position sensing device, a chest strain gauge or an impedance or inductance device to measure chest expansion, an abdominal strain gauge or an impedance or inductance measuring device to measure abdominal expansion, and a
25 microphone for recording snoring and/or breathing sounds.

12. The apparatus of any one of claims 9 to 11, wherein the sensor housings further comprise a third sensor housing having an EMG electrode.

- 17 -

13. The apparatus of any one of claims 9 to 11, wherein the sensor housings further comprise a third sensor housing having an accelerometer arranged to be applied to a limb.
14. The apparatus of any one of claims 9 to 13, wherein the pulse oximeter is of the reflectance or transilluminance type.
15. The apparatus of any one of the preceding claims, wherein each sensor housing is made of plastics material.
16. The apparatus of any one of the preceding claims, wherein the storage means is detachable from the sensor housing.
17. The apparatus of any one of the preceding claims, wherein said processing means encrypts data stored in the storage means.

1/1

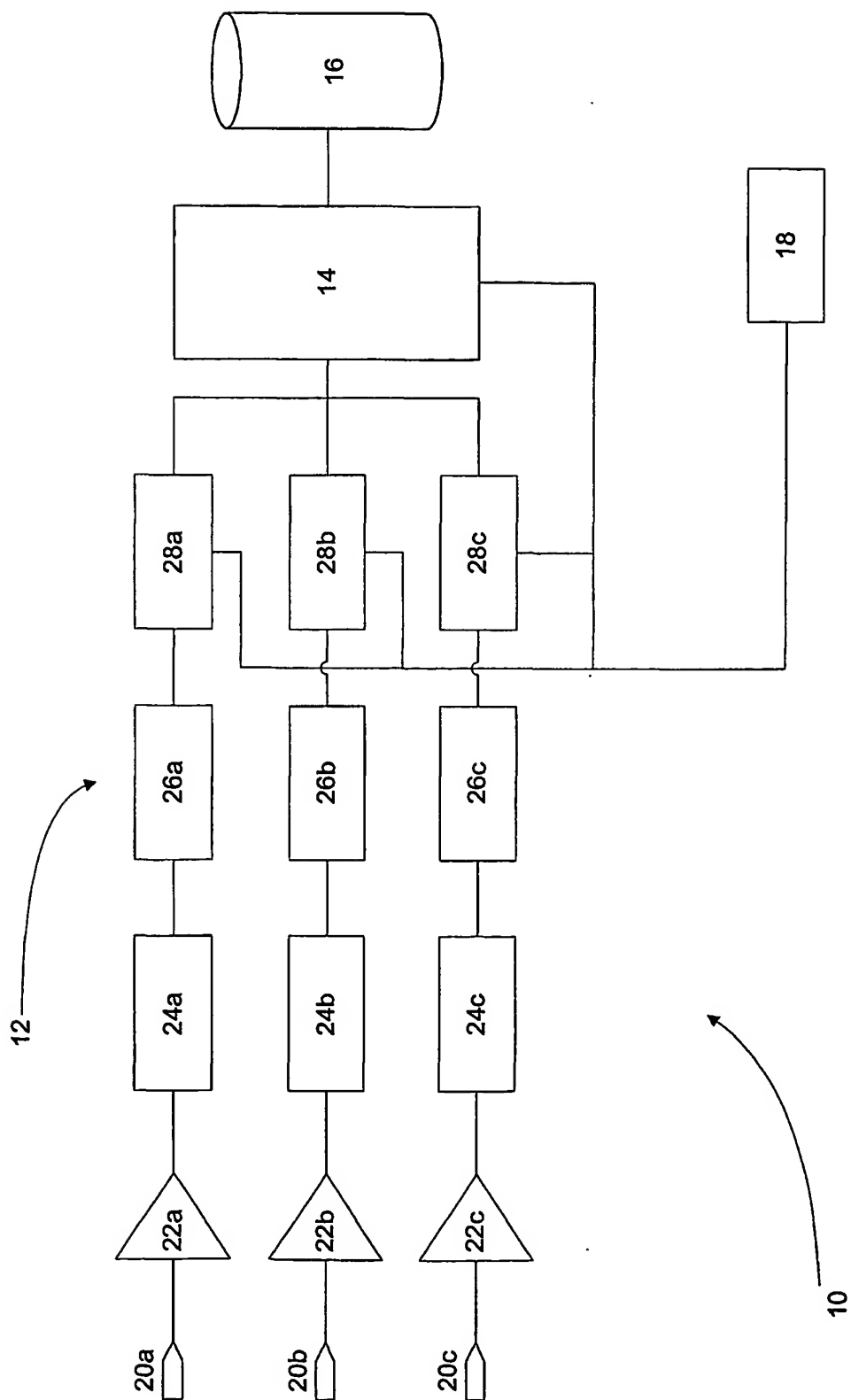
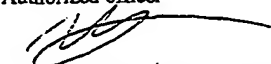


Figure 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00634

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61B 5/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
REFER ELECTRONIC DATA BASE CONSULTED BELOW		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
DWPI: IPC A61B 5/- & keywords; sensor, electrode, storage, storing, memory, RAM, wireless, remote, radio		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 19607222 A1 (BEDRICH) 14 August 1997 See the Espace Abstract	1 - 5, 15 - 17
X	EP 880936 A2 (AKAI et al) 2 December 1998 See col 3, lines 29 to 39; col 7, lines 52 to 58; col 9, lines 14 to 17; col 11 lines 19 to 21	1 - 5, 15 - 17
X	FR 2727850 A1 (ELA MEDICAL SA) 14 June 1996 See the Espace Abstract	1 - 5, 8, 15 - 17
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search		Date of mailing of the international search report
4 July 2001		9 July 2001
Name and mailing address of the ISA/AU		Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		 VINCE BAGUSAUSKAS Telephone No : (02) 6283 2110

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00634

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	Patent Abstract of Japan, JP 2000-232962 A (NEC COMMUN SYST LTD) 29 August 2000 See the whole document	1 - 5, 15 - 17
X	US 5613495 A (MILLS et al) 25 March 1997 See col 3, lines 23 to 41	1 - 6, 15 - 17
X	WO 97/49077 A1 (NOKIA MOBILE PHONES LTD) 24 December 1997 See the Abstract	1 - 5, 8, 15 - 17
A	EP 987047 A2 (BIOTRONIK MESS und THERAPIEGERATE GMBH & CO) 22 March 2000 See the Espace Abstract	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/00634

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
DE	19607222	DE	29620395		
EP	880936	JP	11104088		
FR	2727850	NONE			
JP	2000-232962	NONE			
US	5613495	US	5351695	US	5333616
				US	5317269
WO	97/49077	FI	960362	JP	2000-512414
		JP	2896606	CN	1110857
EP	987047	NONE			
END OF ANNEX					